Notice of Allowability	Application No.	Applicant(s)	
	10/082,443	ALVIS ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *amendment and remarks filed 03/20/06 and telephonic interview of 05/11/06*.

2. ☒ The allowed claim(s) is/are *1-7,9,10,18-58,60,68-86,88-113,115 and 116*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 5/13/02, 11/15/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20060512* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/20/06 has been entered.

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND THE STATUS OF THE CLAIMS

2. The amendment and remarks filed 03/20/06 are acknowledged, entered and considered. Claims 1 and 27 have been amended and claims 115 and 116 have been added. Claims 1-7, 9, 10, 18-58, 60, 68-86, 88-113, 115 and 116 are now pending in the application of which claims 42-58, 60, 68-86 and 88-113 were withdrawn previously as non-elected invention.

ALLOWABLE PRODUCT, REJOINDER OF ALL PREVIOUSLY WITHDRAWN PROCESS CLAIMS

3. Claims 1-7, 9, 10, 18-41, 115 and 116 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 42-58, 60, 68-86 and 88-113 are, directed to the process of making or using an allowable product, previously

withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement as set forth in the Office action mailed on 6/8/04 and 12/22/05 are hereby withdrawn. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claims including all the limitations of an allowable product claim or rejoined process claim are presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

4. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

5. Authorization for this examiner's amendment was given in a telephone interview with Kimberly A. Bolin on 05/11/06.

In the claims:

Amend claims 1-5, 18-25, 27, 28, 30, 31, 34-38, 42, 54-56, 68-73, 76, 89, 102 and 106-111 as follows:

Claim 1: A composition for the treatment of post-surgical articular or incisional pain or discomfort consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and ~~a pharmaceutical agent which is~~ an anesthetic; wherein the composition is formulated to release an effective amount of the ~~pharmaceutical agent~~ anesthetic from the collagen for at least 48 hours, wherein the collagen and ~~pharmaceutical agent~~ the anesthetic are in a ratio of from about 0.5:1 to about 10:1, ~~collagen: pharmaceutical agent~~ and wherein the melting temperature of the composition is from about 42 ^{0}C to about 46 ^{0}C.

Claim 2: The composition of claim 1, wherein the ~~pharmaceutical agent~~ anesthetic is soluble in the dispersion.

Claim 3: The composition of claim 1, wherein the composition is formulated to release an effective amount of the ~~pharmaceutical agent~~ anesthetic from the collagen for at least 72 hours.

Claim 4: The composition of claim 1, wherein the collagen and ~~pharmaceutical agent~~ the anesthetic are in a ratio of from about 1:1 to about 5:1 ~~collagen:pharmaceutical agent~~.

Claim 5: The composition of claim 4, wherein the collagen and ~~pharmaceutical agent~~ the anesthetic are in a ratio of from about 1:1 ~~collagen:pharmaceutical agent~~.

Claim 18: The composition of claim 1, wherein the collagen ~~is at a~~ concentration ~~of~~ is from about 3 mg/ml to about 100 mg/ml.

Claim 19: The composition of claim 18, wherein the collagen ~~is at a~~ concentration ~~of~~ is from about 65 mg/ml.

Claim 20: The composition of claim 18, wherein the collagen ~~is at a~~ concentration ~~of~~ is from about 16 mg/ml to about 28 mg/ml.

Claim 21: The composition of claim 1, wherein the ~~pharmaceutical agent~~ anesthetic ~~is at a~~ concentration ~~of~~ is about 4-30 mg/ml.

Claim 22: The composition of claim 21, wherein the ~~pharmaceutical agent~~ anesthetic ~~is at a~~ concentration ~~of~~ is from about 4 mg/ml to about 10 mg/ml.

Claim 23: The composition of claim 1, wherein a total amount of ~~pharmaceutical agent~~ anesthetic released is from about 5 mg to 1 g.

Claim 24: The composition of claim 1, wherein the effective amount of ~~pharmaceutical agent~~ anesthetic released is from about 2-15 mg per day.

Claim 25: The composition of claim 24, wherein the effective amount of ~~pharmaceutical agent~~ anesthetic released is about 10 mg per day.

Claim 27: A composition for the treatment of post-surgical articular or incisional pain or discomfort consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and bupivacaine; wherein the composition is formulated to release an effective amount of the bupivacaine from the collagen for at least 48 hours, wherein the collagen and bupivacaine are in a ratio of from about 0.5:1 to about 10:1, ~~collagen: bupivacaine~~ and wherein the melting temperature of the composition is from about 42 ^{0}C to about 46 ^{0}C.

Claim 28: The composition of claim 27, wherein the bupivacaine is soluble in the dispersion.

Claim 30: The composition of claim 27, wherein the collagen and bupivacaine are in a ratio of from about 1:1 to about 5:1 ~~collagen:bupivacaine~~.

Claim 31: The composition of claim 30, wherein the collagen and bupivacaine are in a ratio of from about 3.1 to about 4.7:1.

Claim 34: The composition of claim 27, wherein the collagen ~~is at a~~ concentration ~~of~~ is from about 10 mg/ml to about 100 mg/ml.

Claim 35: The composition of claim 34, wherein the collagen ~~is at a~~ concentration ~~of~~ is about 65 mg/ml.

Claim 36: The composition of claim 34, wherein the collagen ~~is at a~~ concentration ~~of~~ is from about 16 mg/ml to about 28 mg/ml.

Claim 37: The composition of claim 27, wherein the bupivacaine concentration ~~of~~ is about 4-30 mg/ml.

Claim 38: The composition of claim 37, wherein the bupivacaine concentration ~~of~~ is from about 4 mg/ml to about 10 mg/ml.

Claim 42: A method for the treatment of post-surgical pain or discomfort in a joint(s) comprising the step of intra-articularly administering to a joint(s) in a patent a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and ~~a pharmaceutical agent which is~~ an anesthetic; wherein the composition is formulated to release an effective amount of the ~~pharmaceutical agent~~ anesthetic from the collagen for at least 48 hours, wherein the collagen and ~~pharmaceutical agent~~ the anesthetic are in a ratio of from about 0.5:1 to

about 10:1, ~~collagen:pharmaceutical agent~~ wherein the melting temperature of the composition is from about 42 ^{0}C to about 46 ^{0}C, and wherein the composition is administered before, during or after a surgical procedure.

Claim 54: The method of claim ~~42~~ 53, wherein the condition is not a degenerative articular process.

Claim 55: The method of claim 42, wherein the composition is formulated to release an effective amount of the ~~pharmaceutical agent~~ anesthetic from the collagen for at least 72 hours.

Claim 56: The method of claim 42, wherein the collagen and ~~pharmaceutical agent~~ the anesthetic are in a ratio of from about 1:1 to about 5:1 ~~collagen:pharmaceutical agent~~.

Claim 68: The method of claim 42, wherein the collagen ~~is at a~~ concentration ~~of~~ is from about 3 mg/ml to about 100 mg/ml.

Claim 69: The method of claim 42, wherein the ~~pharmaceutical agent~~ anesthetic ~~is at a~~ concentration ~~of~~ is about 4-30 mg/ml.

Claim 70: The method of claim 69, wherein the ~~pharmaceutical agent~~ anesthetic ~~is at a~~ concentration ~~of~~ is from about 4 mg/ml to about 10 mg/ml.

Claim 71: The method of claim 42, wherein a total amount of ~~pharmaceutical agent~~ anesthetic released is from about 5 mg to 1 g.

Claim 72: The method of claim 42, wherein the effective amount of ~~pharmaceutical agent~~ anesthetic released is from about 2-15 mg per day.

Claim 73: The method of claim 72, wherein the effective amount of ~~pharmaceutical agent~~ anesthetic released is about 10 mg per day.

Claim 76: A method for the treatment of post-surgical pain or discomfort associated with one or more incisions comprising the step administering to a patient's incision(s) a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and ~~a pharmaceutical agent which is~~ an anesthetic; wherein the composition is formulated to release an effective amount of the ~~pharmaceutical agent~~ anesthetic from the collagen for at least 48 hours, wherein the collagen and ~~pharmaceutical agent~~ the anesthetic are in a ratio of from about 0.5:1 to about 10:1, ~~collagen:pharmaceutical agent~~ wherein the melting temperature of the composition is from about 42 ^{0}C to about 46 ^{0}C, and wherein the composition is administered before, during or after a surgical procedure.

Claim 89: A method for the treatment of post-surgical pain or discomfort in a joint(s) comprising the step of intra-articularly administering to a joint(s) in a patient a composition consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and bupivacaine, wherein the composition is formulated to release an effective amount of the bupivacaine from the collagen for at least 48 hours, wherein the collagen and bupivacaine are in a ratio of from about 0.5:1 to about 10:1, ~~collagen:bupivacaine~~ wherein the melting temperature of the composition is from about 42 ^{0}C to about 46 ^{0}C, and wherein the composition is administered before, during or after a surgical procedure.

Claim 102: The method of claim 89, wherein the collagen and <u>bupivacaine</u> are in a ratio of from about 1:1 to about 5:1 ~~collagen:pharmaceutical agent~~.

Claim 106: The method of claim 89, wherein the collagen ~~is at a~~ concentration ~~of~~ <u>is</u> from about 3 mg/ml to about 100 mg/ml.

Claim 107: The method of claim 89, wherein the <u>bupivacaine</u> concentration ~~of~~ <u>is</u> about 4-30 mg/ml.

Claim 108: The method of claim 107, wherein the <u>bupivacaine</u> concentration ~~of~~ <u>is</u> from about 4 mg/ml to about 10 mg/ml.

Claim 109: The method of claim 89, wherein a total amount of bupivacaine released is from about 5 mg to 1 g.

Claim 110: The method of claim 89, wherein the effective amount of bupivacaine released is from about 2-15 mg per day.

Claim 111: The method of claim 89, wherein the effective amount of bupivacaine released is about 10 mg per day.

REASONS FOR ALLOWANCE

6. The following is an examiner's statement of reasons for allowance: None of the prior art of record either singularly or in combination teach or suggest compositions and methods for using the claimed compositions for the treatment of post-surgical articular or incisional pain or discomfort consisting essentially of an aqueous dispersion of insoluble non-crosslinked type I fibrillar atelopeptide collagen and an anesthetic; wherein the composition is formulated to release an effective amount of the anesthetic from the collagen for at least 48 hours, wherein the collagen and the anesthetic are in a ratio of from about 0.5:1 to about 10:1, and wherein the melting temperature of the composition is from about 42 ^{0}C to about 46 ^{0}C in the manner claimed in claims 1-7, 9, 10, 18-58, 60, 68-86, 88-113, 115 and 116.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

CONCLUSION AND FUTURE CORRESPONDENCE

7. Claims 1-7, 9, 10, 18-58, 60, 68-86, 88-113, 115 and 116 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mohamed/AAM
May 12, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER